§ 108.10 Suspension and reinstatement of permit.

(a) Whenever the Commissioner finds that a permit holder is not in compliance with the mandatory requirements and conditions established by the permit, he shall immediately suspend the permit and so inform the permit holder, with the reasons for the suspension.

(b) Upon application for reinstatement of a permit, the Commissioner shall, within 10 working days, reinstate the permit if he finds that the person is in compliance with the mandatory requirements and conditions established by the permit or deny the application.

(c) Any person whose permit has been suspended or whose application for reinstatement has been denied may request a hearing. The hearing shall be conducted by the Commissioner or his designee within 5 working days of receipt of the request at a location agreed upon by the objector and the Commissioner or, if an agreement cannot be reached, at a location designated by the Commissioner. The permit holder shall have the right to present witnesses on his own behalf and to cross-examine the Food and Drug Administration's witnesses.

(d) Within 5 working days after the hearing, and based on the evidence presented at the hearing, the Commissioner shall determine whether the permit shall be reinstated and shall so inform the permit holder, with the reasons for his decision.

(e) Denial of an application for reinstatement of a permit constitutes final agency action from which appeal lies to the courts. The Commisioner will not stay such denial pending court appeal except in unusual circumstances, but will participate in expediting any such appeal.

§ 108.12 Manufacturing, processing, or packing without a permit, or in violation of a permit.

(a) A manufacturer, processor, or packer may continue at his own risk to manufacture, process, or pack without a permit a food for which the Commissioner has determined that a permit is required. All food so manufactured, processed, or packed during such period without a permit shall be retained by the manufacturer, processor, or packer and may not be introduced or delivered for introduction into interstate commerce without the advance written approval of the Food and Drug Administration. Such approval may be granted only upon an adequate showing that such food is free from microorganisms of public health significance. The manufacturer, processor, or packer may provide to the Commissioner, for his consideration in making any such determination, an evaluation of the potential public health significance of such food by a competent authority in accordance with procedures recognized as being adequate to detect any potential hazard to public health. Within 20 working days after receipt of a written request for such written approval the Food and Drug Administration shall either issue such written approval or deny the request. If the request is denied, the applicant shall, upon request, be afforded a prompt hearing conducted in accordance with § 108.5 (b) and (c).

(b) Except as provided in paragraph (a) of this section, no manufacturer, processor, or packer may introduce or deliver for introduction into interstate commerce without a permit or in violation of a permit a food for which the Commissioner has determined that a permit is required. Where a manufacturer, processor, or packer utilizes a consolidation warehouse or other storage facility under his control, interstate shipment of any such food from the point of production to that warehouse or storage facility shall not violate this paragraph, provided that no further introduction or delivery for introduction into interstate commerce is made from that consolidated warehouse or storage facility except as provided in paragraph (a) of this section.

§ 108.19 Establishment of requirements for exemption from section 404 of the act.

(a) Whenever the Commissioner finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with microorganisms during the manufacture, processing, or

packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he shall promulgate regulations in Subpart B of this part establishing requirements and conditions governing the manufacture, processing, or packing of the food necessary to protect the public health. Such regulations may be proposed by the Commissioner on his own initiative or in response to a petition from any interested person pursuant to part 10 of this chapter.

(b) A manufacturer, processor, or packer of a food for which a regulation has been promulgated in subpart B of this part shall be exempt from the requirement for a permit only if he meets all of the mandatory requirements and conditions established in that regulation.

[42 FR 14334, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977]

Subpart B—Specific Requirements and Conditions for Exemption From or Compliance With an Emergency Permit

§ 108.25 Acidified foods.

(a) Inadequate or improper manufacture, processing, or packing of acidified foods may result in the distribution in interstate commerce of processed foods that may be injurious to health. The harmful nature of such foods cannot be adequately determined after these foods have entered into interstate commerce. The Commissioner of Food and Drugs therefore finds that, to protect the public health, it may be necessary to require any commericial processor, in any establishment engaged in the manufacture, processing, or packing of acidified foods, to obtain and hold a temporary emergency permit provided for under section 404 of the Federal Food, Drug, and Cosmetic Act. Such a permit may be required whenever the Commissioner finds, after investigation, that the commercial processor has failed to fulfill all the requirements of this section, including registration and filing of process information, and the mandatory portions of §§ 114.10, 114.80(a) (1) and (2), and (b), 114.83, 114.89, and 114.100 (b), (c), and (d) of this chapter as they relate to acidified foods. These requirements are intended to ensure safe manufacturing, processing, and packing processes and to permit the Food and Drug Administration to verify that these processes are being followed. Failure to meet these requirements shall constitute a prima facie basis for the immediate application of the emergency permit control provisions of section 404 of the act to that establishment, under the procedures established in subpart A of this part.

(b) The definitions in § 114.3 of this chapter are applicable when those terms are used in this section.

(c)(1) *Registration.* A commercial processor, when first engaging in the manufacture, processing, or packing of acidified foods in any State, as defined in section 201(a)(1) of the act, shall, not later than 10 days after first so engaging, register and file with the Food and Drug Administration on Form FDA 2541 (food canning establishment registration) information including, but not limited to, the name of the establishment, principal place of business, the location of each establishment in which that processing is carried on, the processing method in terms of acidity and pH control, and a list of foods so processed in each establishment. These forms are available from the LACF Registration Coordinator (HFS–618), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at any Food and Drug Administration district office. The completed form shall be submitted to the Center for Food Safety and Applied Nutrition (HFS–565), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Commercial processors presently so engaged shall register within 120 days after the effective date of this regulation. Foreign processors shall register within 120 days after the effective date of this regulation or before any offering of foods for import into the United States, whichever is later. Commercial processors duly registered under this section shall notify the Food and Drug Administration not later than 90 days after the commercial processor ceases